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Standards and Technology Leadership"

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14. ABSTRACT This BAA is providing core program support to develop key capabilities of the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program to lead the evaluation and adoption of open standards and technology for integrating medical devices to support clinical solutions for improving patient safety and healthcare efficiency. Under MD PnP program leadership during the past year, the international ICE standard (Integrated Clinical Environment) Part I was adopted and published by ASTM International as ASTM F2671-2009; progress was made on other interoperability-related standards; a 3-day FDA Workshop on Medical Device Interoperability was held, spinning off a working group to define a prototype regulatory submission; a second version of the MD FIRE contracting language was developed and is being reviewed; our PCA safety demonstration was expanded to a mobile platform to inform future development; notable progress was made in collaborations with the VA and with federal agencies, leading to joint projects and initiatives; and a large 5-year grant was received from NIH/NIBIB.					
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**Annual Report: Medical Device Plug-and-Play Interoperability
Standards and Technology Leadership
Award Number W81XWH-09-1-0705
Principal Investigator: Julian M. Goldman, MD
Period of Performance: 21 September 2009 – 20 September 2010**

[**Note:** The BAA award period has been amended to end March 20, 2011, with the final report due April 20, 2011. Therefore, this report is an Annual Report covering the period of 21 September 2009 through 20 September 2010.]

Introduction

A May 2004 symposium jointly sponsored by TATRC and CIMIT kicked off what became the Medical Device “Plug-and-Play” (MD PnP) interoperability program. Initially focused on creating a standardization framework for interoperability of medical devices in the Operating Room of the Future (ORF), the program collected clinical requirements from anesthesiologists, surgeons, and clinical engineers, and began to define an agenda for standards development. Within a year, we acknowledged that the need for interoperability encompasses the full continuum of healthcare environments, and we developed a strategy to accelerate the development of interoperability technologies as well as standards. The strategy addressed the need for a “sandbox” laboratory environment to facilitate the testing of devices and technologies with proposed standards; the development of a “plug-and-play” system architecture; collaboration with regulatory agencies; leveraging standards and technology to address vendors’ legal concerns; and assuring the clinical relevance of all proposed interoperability solutions.

TATRC support, through a prior BAA and conference grants, has enabled the MD PnP interoperability program to develop key capabilities, to identify and access numerous available resources, and to build collaborations to achieve MD PnP objectives. TATRC’s commitment has enabled us to attract additional program funding from Partners Information Systems, CIMIT, NSF, NIST, and most recently NIH. We have created a medical device interoperability lab at CIMIT in Cambridge, MA, as a multi-institutional, interdisciplinary shared resource. We have developed clinical use cases demonstrating the capability of medical device interoperability to improve patient safety and exhibited these at national meetings. We held an international conference on “Improving Patient Safety through Medical Device Interoperability and High Confidence Software”, jointly sponsored by TATRC and NSF.

Significantly, core program support from TATRC enabled us to lead and achieve the writing and submission of the first medical device integration system standard – the Integrated Clinical Environment (ICE) standard, Part I, which includes functional architecture and risk mitigation strategies for networked patient-centric interoperable medical devices. In addition, we led a successful collaborative effort of three major healthcare providers to develop and adopt sharable interoperability contracting language for use in the procurement of medical devices and related equipment. We facilitated the endorsement by seven medical societies (including the American Medical Association) of medical device interoperability for improving patient safety. We worked with three companies on DoD SBIR projects to develop a first-responder ICE Supervisor. TATRC BAA support has been instrumental in providing “program glue” to effectively leverage these highly interdependent and synergistic activities to realize program objectives.

Body of Report

The MD PnP Program has become a recognized leader in medical device interoperability to support clinical solutions for improving patient safety and healthcare efficiency. Interoperability will enable the creation of complete electronic health records and will introduce error resistance into networked medical device systems. We are producing a standardization framework

consisting of a functional architecture and requirements for implementing standards in a manner that will support interoperability for effective clinical deployment. This requires critical evaluation (or “gap analysis”) of potentially suitable candidate standards, as well as the modification of existing standards and development of new standards for implementation in the MD PnP standardization framework. By leveraging available standards, we expect to accelerate the MD PnP standards framework development, so that useful candidate standards can be vetted and demonstrated within another three to five years. This includes defining an appropriate regulatory pathway for networked medical device systems in partnership with the U.S. FDA, and developing the MD PnP Lab as a “sandbox” populated with medical devices and test equipment to serve as a vendor-neutral environment to perform interoperability testing and conformance testing to evaluate proposed standards. Building on what has been accomplished to date, we have sought to leverage areas of traction around five key themes identified for this work:

- Standards development
- Open clinical platform development
- Clinical and engineering requirements for MD PnP
- Regulatory pathway
- Inclusion of device interoperability in the national health IT agenda

Since the program’s inception, more than 750 clinical and engineering experts, and representatives of more than 90 companies and institutions have participated in four plenary workshops / conferences, working group meetings, and focus groups to contribute to ongoing program activities that helped shape the common goals. Our geographically dispersed, interdisciplinary, multi-institutional team of collaborators has included participants from: Kaiser Permanente, Johns Hopkins Medicine, Draper Laboratory, FDA, NIST, university computer and information science groups at Pennsylvania, Illinois/Urbana-Champaign, Kansas State, New Hampshire, Waterloo (Canada), and Wiener Neustadt (Austria), Draeger Medical Systems, Philips Healthcare, DocBox Inc., Moberg Research Inc., LiveData Inc., MITRE Corporation, Lockheed Martin Corporation, IXXAT, NSF/CPS (Cyber Physical Systems), Geisinger Health System, and the Partners HealthCare System community (MGH Anesthesia, Biomedical Engineering at MGH and Brigham & Women’s Hospital, and Partners HealthCare Information Systems).

For the period of this grant, we proposed the following objectives:

Standards Development

- Address remaining formal comments on the ICE standard (ASTM F-2761), Part I, resulting from balloting within ASTM, and see it through to publication.
- Convene the working and writing groups for the next part of the ICE series of standards (probably the “network controller” and “device models”); manage their work to produce preliminary draft standards.
- Complete the gap analysis of the capability of the IEEE 11073 medical communication series of standards to support the use cases outlined in Part I of the ICE standard in partnership with DoD- and NSF-funded collaborators.
- Participate in standards activities synergistic with ICE, e.g. IEEE 11073 and IEC 80001 (risk management of medical devices connected to IT systems).
- Incorporate results of ICE platform development (see below) to improve the ICE series of standards.

Open Clinical Platform Development

- Leverage the CIMIT-funded development of a prototype clinical platform for improving PCA safety to assure future extendibility of the prototype concept by identifying engineering requirements related to a broader implementation of an open ICE development platform.
- Develop architecture for the clinical prototype platform to conform to the ICE standard.

- Identify requirements for the broader open ICE platform to support iterative clinical applications.

Clinical and Engineering Requirements for MD PnP

- Refine the existing database of clinical scenarios and categorize in terms of ICE elements and safety-critical factors, to enhance its utility as a use case repository for use by the interoperability development community.
- Identify the most important medical devices to include in interoperability development efforts.
- Apply our use case / clinical requirements analysis methodology to the ICE use cases.

Regulatory Pathway

- Continue collaborating with the FDA on standards, on gap analysis, and on identifying a regulatory pathway for ICE-compliant medical devices.
- Work with the FDA to plan a workshop on medical device interoperability for December 2009 or Q1 2010.

Program Development and Management

- Continue to build collaborations with patient safety and technical organizations.
- Provide oversight and coordination to the various collaborative groups working on projects related to the ICE platform (ICE Platform Integration Coordination working group: ICE-PIC).
- Continue to work with healthcare delivery organizations to further develop the MD FIRE contracting language and to utilize it in appropriate RFPs and contracts.
- Enable the PI to play a coordinating role for the various TATRC-funded SBIR projects aimed at furthering medical device interoperability (MD PnP “glue”).
- Leverage the NSF-funded work to support TATRC goals, and vice versa, to enhance federally-funded outcomes.
- Investigate Center or Program Grants that could support development and utilization of the MD PnP program and lab as a national resource for medical device interoperability.

Research Accomplishments

Standards Development

Objective 1: Address remaining formal comments on the ICE standard (ASTM F-2761), Part I, resulting from balloting within ASTM, and see it through to publication.

A multi-institutional writing group, led by Dr. Goldman and convened by ASTM International Committee F29 – including engineers and standards experts from Partners HealthCare System, the FDA, Draper Lab, Draeger Medical, MITRE Corporation, Philips Medical, DocBox Inc., and University of Pennsylvania – produced the preliminary draft of Part I of the multi-part ICE standard (“Integrated Clinical Environment”) that embodies the elements of the overall technology ecosystem to safely implement networked medical device systems. This draft was submitted by ASTM F29 as a New Work Item Proposal (NWIP) to the IEC/ISO international standards development organizations in late 2007. It received a tie vote in ISO, which was insufficient for adoption as a New Work Item. Many comments were submitted – supportive comments from healthcare delivery systems and criticism from companies with proprietary interests.

The ASTM ICE writing group systematically reviewed and addressed all 161 submitted comments on Part I, a lengthy effort but one that contributed to an improved standard: Part I was re-scoped and re-named “General requirements and conceptual model,” and outlines the more specific ICE parts still to be written. During the period of this grant, ICE Part I was successfully balloted within ASTM and additional comments were addressed. ICE Part I, “Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE),” was published by ASTM as F2761-2009 in December 2009. The standard

started being used immediately by international standards bodies and consortia, small companies with DoD SBIR and STTR support, and universities that are doing related research.

Objective 2: Convene the working and writing groups for the next part of the ICE series of standards (probably the “network controller” and “device models”); manage their work to produce preliminary draft standards.

Because the effort to systematically address the ICE Part I comments required substantial rewriting of the draft standard within officially convened standards meetings, the launch of work on subsequent parts had to be postponed. The ICE conceptual model that evolved made it clear that development of Parts II and III (device and system models, and the network controller) would need to proceed in parallel, due to the interdependencies of the proposed requirements and functionality. We convened a multi-institutional ASTM writing group in September 2009, including several new participants from small businesses that had received DoD SBIR Phase I awards for ICE-related development. Initial drafting of Parts II and III was begun. This meeting clarified that the development of device models requires broader collaboration and expertise.

Follow-on work from the January 2010 FDA Workshop on Medical Device Interoperability (see **Objectives 12 & 13**) is producing information about device models and the network controller that will inform development of the standard. AAMI (Association of Advanced Medical Instrumentation) has created a new ad-hoc working group that is building on our work and is facilitating the involvement of industry (via AdvaMed).

We expect that continued development of the ICE standard will be informed by collaborative work being done by Moberg Research Inc. and LiveData Inc. through Phase II DoD SBIRs, as these projects are producing device models that will also inform the future development and architecture of an open ICE development platform. In addition, collaborative work now underway with two university computer science and engineering groups will also inform both the ICE standard and the open ICE development platform. With this important work ongoing, we have concluded that pursuing the lengthy New Work Item Proposal (NWIP) pathway at this time will not yield the timely results we can achieve through less formal working groups that are learning from real-world experience. Our expectation remains that the work of these collaborators will later feed into the formal standards development and submission of ICE Parts II and III, but we feel it is too early to pursue the NWIP process now.

Objective 3: Complete the gap analysis of the capability of the IEEE 11073 medical communication series of standards to support the use cases outlined in Part I of the ICE standard in partnership with DoD- and NSF-funded collaborators.

Several clinical scenarios were incorporated into the ICE Part I standard. The ICE-PAC – a team of MD PnP collaborators that includes leaders of medical device communication standards groups, medical device manufacturers (such as Philips, GE, and Draeger), and small system integrators – has been performing detailed workflow analysis of these use cases and analyzing the ability of the IEEE 11073 set of standards to meet these requirements. NIST has recently been invited to join the ICE-PAC effort. The group has completed most of the functions in ICE use cases to date, and their work is feeding other MD PnP-related activities, as well as enabling collaborative work with other organizations, notably the industry-driven IHE (Integrating the Healthcare Enterprise). Given the scope of the ICE-PAC gap analysis and our outreach to AAMI, we anticipate potential AAMI collaboration to help advance this effort.

Objective 4: Participate in standards activities synergistic with ICE, e.g. IEEE 11073 and IEC 80001 (risk management of medical devices connected to IT systems).

In November-December 2009 the MD PnP program and collaborators contributed content to Technical Note 905, written for the HITSP (Healthcare Information Technology Standards Panel) Common Device Connectivity Extension/Gap, which seeks to define requirements for

more tightly integrating medical devices into electronic medical record systems (EMRS). In response to the request for public comment in December, the program and collaborators submitted further improvements. The Note was adopted and published by HITSP in January 2010 (http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=905).

We hosted the meeting of the ISO/IEC TC121 subcommittee on Lung Ventilators and Related Devices in January, and hosted the meeting of the ISO/IEC subcommittee on Airway Devices in February. Also in February Dr. Goldman attended the IEC 80001 standards meeting on risk management of medical devices connected to IT systems; the ICE standard will have a strong impact on this work. In April we hosted a meeting of the ISO/IEC JWG7 on 80001. (IEC 80001 was published as an international standard in October 2010.)

In June Dr. Goldman chaired the annual ISO TC121 standards meeting. At that meeting, the joint working group on anesthesia workstations also convened, and the critical care ventilator group approved language for the ISO/IEC FDIS 80601 standard that allows for a timed ventilatory pause when clinically indicated. We hosted the meeting of the ISO/IEC JWG on Respiratory Gas Monitors in August. The ongoing participation of Dr. Goldman and other MD PnP team members in these standards activities is critical because devices under the purview of different companies will have to conform to common interoperability specifications, including ASTM ICE.

Objective 5: Incorporate results of ICE platform development to improve the ICE series of standards.

Because this objective is contingent on platform development work that could not be completed during the past year due to unavailability of appropriate engineering resources, there is nothing to report at this time.

Open Clinical Platform Development

Objective 6: Leverage the CIMIT-funded development of a prototype clinical platform for improving PCA safety to assure future extendibility of the prototype concept by identifying engineering requirements related to a broader implementation of an open ICE development platform.

Although we have been successful in attracting collaborators who want to work with us to advance medical device interoperability, these geographically distributed organizations work primarily on their own campuses or company premises, where they have their own tools and development environments. They have only occasionally convened at the MD PnP Lab to integrate their efforts, for example, for a demonstration implementation. However, in August we were able to reconvene the international team that implemented our PCA safety use case. They installed their updated components on a mobile cart in our lab, and gave talks and a demonstration to a group of 20 invited biomedical and clinical engineers and managers from Partners HealthCare and several local collaborators – a very successful event in sharing our results.

Previously we have not had sufficient resources to enable hiring dedicated engineering personnel for the program to pursue this platform development work. At the end of August, we hired an embedded systems engineer who had been working with us as a collaborator at the University of Pennsylvania for several years on our demonstration implementations. During September 2010 he started working on a detailed re-engineering of our PCA safety demonstration, and he will enable us to progress on our platform development as well as multiple internal projects.

Objective 7: Develop architecture for the clinical prototype platform to conform to the ICE standard.

Because our goal is ICE conformance for interoperability solutions, achievement of this objective has been delayed due to the challenges in completing the ICE standard.

Objective 8: Identify requirements for the broader open ICE platform to support iterative clinical applications.

One critical component of an ICE platform is the data logger, which addresses safety, liability, and regulatory needs. Although limited in function for our initial PCA prototype, this implementation is elucidating some of the issues that will need to be addressed in Parts II and III of the ICE standard, as well as in a broader open ICE platform. We are also exploring the capabilities required to “play back” data from the data logger to re-create clinical events.

Our plans for a scientific exhibit at HIMSS in March 2010, where we hoped to get input on these requirements, had to be deferred because of the importance of the FDA Workshop planning and follow-up, and the critical activity of seeking long-term funding.

Clinical and Engineering Requirements for MD PnP

Objective 9: Refine the existing database of clinical scenarios and categorize in terms of ICE elements and safety-critical factors, to enhance its utility as a use case repository for use by the interoperability development community.

The activity of identifying and refining high-level clinical scenarios, in order to lay the foundation for developing technical specifications for medical device interoperability, is ongoing. The clinical use cases we have collected are being used as highly-valued input for work by our industry and university collaborators, and several archetypal use cases representing different aspects of interoperability were included in Annex B of the ICE standard, Part I.

Collaborative work with DocBox Inc. and with the companies participating in the ICE-PAC gap analysis activity is contributing to the refinement of clinical requirements and use cases. This effort is yielding detailed workflow and requirements from an engineering perspective, and is expected to feed back additional details into the workflow documentation. Project-specific work under other funding will also yield refinements of the use cases involved in those projects.

Resource constraints and emerging and shifting priorities have limited our ability to complete the necessary analysis, categorization, and amplification to make our database of use cases a sharable resource. This is still an important program goal, as we regularly receive input that these use cases are perceived as one of the program’s assets. Our summer interns worked on a design for a web-deployable secure requirements database to facilitate capture of critical elements as we and collaborators add scenarios. Feedback on the design is being given by collaborators at FDA and NIST, who see the broad applicability of this database. One of the objectives of our Option-Year request is to complete a robust design and implementation of this use case repository, as well as a plan for managing a web-based interface to facilitate broader collection of new use cases and refinement of existing ones, while protecting the integrity of the database.

Objective 10: Identify the most important medical devices to include in interoperability development efforts.

We have been working on this as part of the development of specific use cases (e.g. PCA safety), and we expect to complete a sharable list within the next six months.

Objective 11: Apply our use case / clinical requirements analysis methodology to the ICE use cases.

The ICE-PAC team is using our methodology to guide their analysis of the ICE use cases.

Regulatory Pathway

Objective 12: Continue collaborating with the FDA on standards, on gap analysis, and on identifying a regulatory pathway for ICE-compliant medical devices.

An engineer from the FDA's Center for Devices & Radiological Health (CDRH) has been a regular participant in the team that has been developing the ICE standard, and has participated with the ICE-PAC team as well. He is a senior advisor for our program and is frequently consulted.

As follow-up to the FDA workshop on Medical Device Interoperability held in January (see **Objective 13**), there are two groups meeting on an ongoing basis. The organizing/steering committee for the workshop – which includes Dr. Goldman and Ms. Whitehead – meets biweekly by phone to discuss development of standards, guidance documents, and relevant related activities.

The steering committee is also leading a working group of 15-20 participants from industry, clinical care, standards development organizations, and regulatory agencies that are developing a detailed risk / regulatory model for an integrated “prototype” regulatory submission. This instantiated model – essentially a combination of existing devices and interoperability functionality (virtual at this point) for a specific use case – is intended to allow FDA and interoperability stakeholders to identify and address issues in the process for regulatory approval. This group is holding weekly teleconferences and is making good progress. A face-to-face meeting at the FDA is planned for November 2010.

Objective 13: Work with the FDA to plan a workshop on medical device interoperability for December 2009 or Q1 2010.

Following months of planning by the organizing committee (including Dr. Goldman and Ms. Whitehead as well as representatives from the FDA and the Continua Health Alliance, the co-sponsors), the FDA Workshop on Medical Device Interoperability was held on January 25-27, 2010, at the FDA in Silver Spring, MD. More than 150 technical, clinical, and regulatory experts attended in person, including medical device manufacturers, IT and communications vendors, healthcare providers, researchers, consultants, and government experts from the FDA, NIH, VA, NSF, and NIST. Another 50-60 participated in the live web-cast of the workshop. The program consisted of plenary speakers to define the issues and set the context, use case presentations and discussions by a range of stakeholders, and breakout sessions to allow groups with similar interests to target important issues and to delve deeper into the problems and possible solutions.

This workshop was the strongest action the FDA has taken to show its commitment to medical device interoperability. The heads of CDRH and the Office of Device Evaluation both spoke, and 25 FDA staff were in attendance. The workshop was considered an informative, educational event by those who attended. An important outcome of the workshop was the shared recognition that improved, interoperable product designs are the key to reducing adverse events (e.g. via automated safety interlocks) and enabling new clinical treatments that are greater than the sum of their components. Slides and streaming video of the workshop presentations are available at our MD PnP web site: http://mdpnp.org/FDA_Interop_Workshop.php. These pages have been receiving about 70 hits per week.

Program Development and Management

Objective 14: Continue to build collaborations with patient safety and technical organizations.

Our successful approach to convening and facilitating diverse MD PnP stakeholders has been a key part of the program, as evidenced by our increasing collaborations with groups interested in achieving medical device interoperability.

We have engaged with Lockheed Martin Corporation on a collaborative project (currently internally funded by Lockheed) to use simulation in virtual clinical environments to facilitate investigation of safety aspects of medical device interoperability and the proposed ICE platform. The first prototype, based on ICU alarm scenarios provided by our program, was deployed in the MD PnP Lab in August, and was shown to a cross-institutional group of CIMIT consortium members in late September, generating great interest.

We have had preliminary discussions with Intel about potentially collaborating on projects to help develop building blocks for the ICE platform.

Our ties with the Office of the National Coordinator for Health IT (ONC), NSF, and NIST were greatly strengthened during the past year. At Dr. Goldman's invitation, Dr. Charles Friedman, the Chief Scientific Officer at ONC, gave a keynote address at the FDA Workshop on Medical Device Interoperability. Currently Dr. Friedman is working on an ONC "adoption" of our NIBIB grant as an affiliate of the ONC-funded SHARP (Strategic Health IT Advanced Research Projects) grants. We worked with a new contact at NIST to develop a proposal to work collaboratively on using NIST's internal Data Flow System to implement ICE use cases as a proof of concept of medical device interoperability.

Existing relationships with the VA have led to further collaboration. After several discussions with us over the past two years, the VA Standards & Technology group held an October meeting focused on medical device interoperability, with the aim of deciding how the VA can become more involved in making this a reality. Dr. Goldman gave the keynote address.

Objective 15: Provide oversight and coordination to the various collaborative groups working on projects related to the ICE platform (ICE Platform Integration Coordination working group: ICE-PIC).

Although no specific new projects were generated by ICE-PIC, individual collaborative groups are working on their own ICE-related projects, and our program has remained a touchstone for sharing learnings and ideas from this work.

Objective 16: Continue to work with healthcare delivery organizations to further develop the MD FIRE contracting language and to utilize it in appropriate RFPs and contracts.

During the past year we have worked with lawyers and others on a next version of the MD FIRE contracting language. The VA is currently having a look at this version, with an interest in getting VA adoption. In other encouraging developments, the U.K. National Health Service has used and referenced the MD FIRE document for Health IT system requirements, and CIMIT is discussing how to get MD FIRE adopted by its consortium member institutions. This will be very helpful in developing a strategy for broader adoption.

Dr. Goldman convened a group of healthcare delivery organizations at the HIMSS10 conference in March 2010 and again at the AAMI meeting in late June to discuss the adoption of the MD FIRE contracting language. This group is also defining customer-driven interoperability requirements and sharing strategies for obtaining data from devices to enhance electronic health record systems (EHRs). As a result, we have started developing an MD FIRE appendix of specific device interoperability requirements for use by procurement officers, device manufacturers, and standards developers. Many concepts from ICE and from MD PnP are being discussed and adopted in groups such as this.

Objective 17: Enable the PI to play a coordinating role for the various TATRC-funded SBIR projects aimed at furthering medical device interoperability (MD PnP "glue").

This objective has decreased in relative importance, as there was only a single Phase II SBIR award related to ICE. However, that award was to Moberg Research, with which we have

ongoing discussions and collaboration. Dr. Goldman will continue to identify and highlight synergies he observes between relevant TATRC-funded activities.

Objective 18: Leverage the NSF-funded work to support TATRC goals, and vice versa, to enhance federally-funded outcomes.

Dr. Goldman was invited to participate on the NSF Computer & Information Science & Engineering (CISE) Advisory Committee, and attended his first meeting in October 2009. He participated in two interagency meetings where medical device interoperability was discussed in terms of a government agency collaborative effort. At the end of October 2009 he attended the NSF-sponsored invitation-only "Discovery and Innovation in Health IT" workshop, designed to explore near- and long-term challenges and opportunities in healthcare IT, and to identify mutual interests and synergies among participants. In early December Dr. Goldman convened a meeting hosted by NSF and attended by TATRC, NSF, NIH, NIST, and the VA, to discuss strategies for long-term collaboration on interoperability research and platform development. Dr. Goldman was on the Steering Committee for and participated in the FDA-sponsored Medical Robotics Workshop in February, which included standards experts, clinicians, and government agencies such as FDA and TATRC, and where elements of ICE were successfully introduced. We continue our ongoing investigation of appropriate pathways for support of this work through NIH, NSF, ONC, NIST, and the VA.

Objective 19: Investigate Center or Program Grants that could support development and utilization of the MD PnP program and lab as a national resource for medical device interoperability.

The concept of the MD PnP "sandbox" Lab has been a key component of the MD PnP vision, and making the Lab operational in 2006 provided a physical anchoring point for the program and enabled the implementation of use case demonstrations to illustrate the concepts and feasibility of MD PnP. Partners HealthCare Information Systems engineers provided a "virtual medical network" infrastructure to support multiple devices and a test environment. The Lab's potential was demonstrated during the June 2007 HCMDSS / MD PnP Workshop, when nine interoperability-related demos were brought in by industry and academic institutions.

In January we submitted a \$10.6M four-year proposal to the National Institute of Biomedical Imaging & Bioengineering (NIBIB) for a Quantum grant to develop a prototype healthcare intranet based on an open ICE platform. In May we submitted a brief supplement to our proposal, which included letters of support from the CIO of Partners Healthcare and the Senior VP for Administration at Mass General. To illustrate the patient safety need for the ICE platform we were proposing, we also included excerpts from a Boston Globe article on the death of a patient at MGH that was related to the issue of lack of smart alarms. In August we were asked for additional information, and in September we received a Quantum grant at \$9.9M for 5 years. We are collaborating with three universities and three small companies, and we expect this project work to provide significant results usable by other projects (both ours and those of our collaborators) and to inform further ICE standards development. This project will enable us to build up our lab resources (people, devices, and software tools) and should position us to apply eventually for a center grant.

We collaborated with the University of Pennsylvania on an NSF proposal to do more detailed research on the safety factors in implementing medical device interoperability. This project has also been funded by NSF for 5 years, and will be highly synergistic with our NIBIB project. We worked closely with CIMIT and two CIMIT consortium member institutions, VA Boston and Boston University, to assist them in proposing device interoperability-related projects for FY11 CIMIT funding. We also submitted a CIMIT proposal of our own to implement a pre-clinical platform based on our prior PCA use-case work. All three have received \$98K grants in FY11 for projects that will enable device and EHR interoperability. In June we submitted a proposal to

the National Institute of Standards & Technology (NIST) for a collaborative project with a group of NIST scientists to model ICE-defined device and network controller functionality. This has been funded at \$100K for FY11. All of these projects will make significant use of our lab.

The group at Lockheed that is working with us on virtual clinical environments provided a small contract to us for assistance with their Phase I project. More importantly, they installed \$100K of equipment in our lab to support the virtual world application – this greatly enhances our lab capabilities.

Key Research Accomplishments

- **ASTM “ICE” standard.** A multi-institutional writing group led by the MD PnP program and convened by ASTM International – including engineers and standards experts from industry, healthcare systems, government and academia – produced Part I of the multi-part ICE standard (“Integrated Clinical Environment”) that embodies a framework technology ecosystem to safely implement integrated multi-vendor medical device systems. These building blocks will enable flexible development and deployment of decision support and advanced monitoring systems. Part I was published as ASTM F2761-2009 and development of subsequent parts is underway. Work on the ICE standard has guided and informed other related standards work, e.g. the IHE PCD domain, gap analysis of the ability of the IEEE 11073 set of standards to support the clinical use cases described in ICE, and the recently released HITSP Technical Note 905 (http://bit.ly/HITSP_TN905).
- **Interoperability contracting language.** The MD PnP program led a collaborative project of Kaiser Permanente, MGH/Partners HealthCare, and Johns Hopkins Medicine to jointly author an interoperability procurement guide. In October 2008 we published this document as a “call to action” to improve patient safety by recommending that medical device interoperability requirements be included as an essential element in vendor selection criteria and procurement processes. This collaboration has produced sample RFP and contracting language that is being shared with other institutions as well as device manufacturers (MD FIRE: Medical Device Free Interoperability Requirements for the Enterprise, http://bit.ly/MD_FIRE_Page). An updated version of MD FIRE is currently being reviewed by the VA and other healthcare systems.
- **Medical society endorsements/end-user “pull”.** From March 2007 to June 2009, through MD PnP program leadership, the need for medical device interoperability was endorsed by seven medical societies – the American Medical Association, Anesthesia Patient Safety Foundation, the American Society of Anesthesiologists, the Society of American Gastrointestinal Endoscopic Surgeons, the World Federation of Societies of Anaesthesiologists, the Society for Technology in Anesthesia, and the Massachusetts Medical Society. These endorsements continue to be a powerful motivator for other groups considering deeper engagement. Example text:

Intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind. We also recognize that, as in all technological advances, interoperability poses safety and medico-legal challenges as well. The development of standards and production of interoperable equipment protocols should strike the proper balance to achieve maximum patient safety, efficiency, and outcome benefit.
- **Collaborative R&D.** The Joint Workshop on High Confidence Medical Devices, Software, & Systems (HCMDSS) and MD PnP Interoperability, funded by TATRC and NSF and held in June 2007, led to extensive collaborations with the University of

Pennsylvania and the University of Illinois at Urbana-Champaign. The Cyber Physical Systems program at NSF funded each of them for three-year projects (2008-2011) to work with our program to investigate safety-critical aspects of networked medical device systems, and has just awarded a new five-year grant to University of Pennsylvania that will be synergistic with MD PnP efforts. TATRC funded five companies through SBIRs to develop ICE-compliant systems, and we worked with four of them: LiveData Inc., Moberg Research Inc., Linea Research Corp., and GCAS Inc. The collaboration with Moberg Research is continuing through a Phase II award. In July 2009 MD PnP convened our active collaborators for two days to share information and discuss additional potential collaboration opportunities to develop an open ICE-compliant platform. These activities have informed the research priorities for NSF and NITRD.

- **CIMIT MD PnP Lab.** The CIMIT MD PnP Interoperability Lab opened in May 2006 to provide a vendor-neutral “sandbox” to evaluate the ability of candidate interoperability solutions to solve clinical problems, to model clinical use cases (in a simulation environment), to develop and test related network safety and security systems, and to support interoperability and standards conformance testing. The Lab has been used by our university collaborators to further develop demonstrations of interoperability-based patient safety improvements (improving the safety and quality of portable x-rays and of patient-controlled analgesia systems that are used for pain management). Lockheed Martin Corporation recently installed a prototype of their virtual clinical world simulation tool, which is being further developed during the coming year. We are currently working on smart alarms projects in the Lab, and we intend to host additional inter-institutional projects there.
- **Regulatory pathway.** The MD PnP program has from its inception worked closely with the U.S. FDA to identify a regulatory pathway that will support the MD PnP concept – one which will not require re-validation or re-clearance of an entire networked system as each new independently validated device is added to the medical network. Over the past five years we have studied and elaborated the issues and solutions surfaced by medical device interoperability stakeholders. An important step towards FDA buy-in was the three-day workshop on medical device interoperability planned by the MD PnP program in conjunction with the Continua Health Alliance and the FDA and held at the FDA in January 2010. This workshop brought together over 200 participants from stakeholder communities to explore the issues and roadmap potential solutions (<http://bit.ly/5Kj5X9>). The workshop is being followed up by the development of a prototype regulatory submission of an interoperable medical device system by a group comprised of companies, standards organizations, clinical and legal participants, and the FDA.
- **Relationships with federal agencies.** In addition to the FDA, the MD PnP program has been working with NIST, NSF, the Office of the National Coordinator for Health IT, the VA Office of Joint Interoperability Ventures, and an interagency group convened by the White House Homeland Security Council to explore a pathway for medical device interoperability as a critical part of a health information sharing environment. Recognition of the critical role of device interoperability in the national health IT agenda has increased greatly over the past year, as evidenced by the ONC HIT presentation of a meaningful-use-to-device-interoperability crosswalk at the January 2010 FDA workshop (<http://bit.ly/bh1ekG>), as well as recent interest expressed by Aneesh Chopra, the Federal CTO, in hosting a workshop to address specific device interoperability issues.
- **Non-DoD Funding.** We received a 5-year \$9.9M grant from NIH/NIBIB, a significant vote of confidence in our work and achievements to date. A close collaborator received a large 5-year grant from NSF Cyber Physical Systems, with our program as an important partner.

In addition to the specific achievements above, the MD PnP program has in the past year gained increasing traction through our collaborative relationships. The web of connections among people in our community of interest continues to generate new connections to supportive individuals in government agencies, healthcare institutions, and other organizations who are helping to further the aims of the program. CIMIT continues to provide space for the MD PnP program for both the Lab and for offices.

Reportable Outcomes

24+ Meetings:

- September 14-16 2009 – ICE Parts II and III meeting at CIMIT; first meeting for continuing work on subsequent parts of the ICE standard
- October 4-5 2009 – Cerner Health Conference: scientific exhibit on medical device interoperability developed by MD PnP collaborators at Kansas State University
- October 7-9 2009 – Continua Health Alliance Summit in Boston; Dr. Goldman chairs the Use Case Committee
- October 16 2009 – meeting of NSF Computer & Information Science & Engineering (CISE) Advisory Committee, Washington DC
- October 29-30 2009 – invitation-only “Discovery and Innovation in Health IT” interagency workshop sponsored by NSF, San Francisco, CA
- December 2 2009 – federal agency interoperability meeting, NSF, Washington DC
- January 25-27 2010 – FDA-Continua-CIMIT Workshop on Medical Device Interoperability, Silver Spring, MD
- February 10-12 2010 – Continua Health Alliance Summit in San Diego; Dr. Goldman chairs the Use Case Committee
- February 19 2010 – Medical Robotics Workshop, FDA, Silver Spring, MD
- March 2 2010 – multi-institutional meeting on interoperability requirements and on obtaining EMR data from devices, at HIMSS10, Atlanta, GA
- April–Sept 2010 – weekly teleconference calls of the Prototype Regulatory Submission team
- April–Sept 2010 – bi-weekly teleconference calls of the FDA interoperability workshop Steering Committee
- April 19 2010 – visit by Dr. Goldman with two other CIMIT leaders to AHRQ to present CIMIT’s ICE initiative, Washington DC
- May 7 2010 – meeting of NSF CISE Advisory Committee, Washington DC
- May 17-18 2010 – ASTM International F29 meeting, New Orleans, LA
- June 14-18 2010 – ISO TC121 meeting, Queenstown, New Zealand
- July 26 2010 – FDA-FCC workshop on wireless use in healthcare
- July 27 2010 – meeting with Aneesh Chopra, U.S. Chief Technology Officer
- August 5 2010 – meeting with Brian J. Masterson, Col, USAF, MC, CFS, Command Surgeon, Headquarters Air Force Reserve Command, to discuss potential intersects between our work and his forward planning efforts
- August 2-9 2010 – convened international team for Medical Device PnP Platform™ (MD MP3™) to complete PCA safety use case implementation on a mobile cart in our interoperability lab
- August 9 2010 – MD MP3™ Presentation Day (technical talks and demonstration of mobile cart implementation)
- August 11 2010 – meeting of NSF Cyber Physical Systems Program investigators, Washington DC
- August 23 2010 – MD PnP strategic planning meeting
- August 25 2010 – meeting with Intel to discuss potential collaboration

14 MD PnP Presentations:

Dr. Goldman delivered invited presentations on Medical Device Interoperability for Improving Patient Safety and Healthcare Efficiency to the following groups during the past year:

- Sept 10 2009 at Medical Device Connectivity Conference, Boston, MA
- October 5 2009 at Cerner Health Conference, Kansas City, MO
- October 6 2009 at HealthMart 09 Conference, Worcester, MA
- November 3 2009 at Kaiser Permanente, Oakland, CA
- February 25 2010 keynote address at International Symposium on IT-Networks in Hospitals, Germany
- March 24 2010 at Grand Rounds at Mt. Sinai Medical Center, New York, NY
- May 3 2010 at American Thoracic Surgeons annual meeting, Toronto, Canada
- May 21 2010 at Harvard Medical School, Boston, MA
- June 3 2010 at 13th Asian Australasian Congress of Anesthesiologists, Fukuoka, Japan
- June 24 2010 on an IEEE webinar broadcast to Lockheed Martin employees
- June 26 2010 at the AAMI annual conference, Tampa, FL
- July 14 2010 keynote address at INCOSE annual meeting, Chicago, IL
- July 21 2010 on a webinar broadcast by ECRI Institute
- August 17 2010 at the Veterans Administration Joint Interoperability Ventures meeting, Washington DC

Web Site:

- www.mdnp.org is maintained as a major communication vehicle for the program – provides access to ICE standard, MD FIRE contracting language, publications, posters, links to streaming video of talks from plenary meetings and from the FDA Workshop

Manuscripts/Publications:

- Whitehead SF, Goldman JM, "Connectivity to Improve Patient Safety: Making Medical Device 'Plug-and-Play' Interoperability a Reality," *Patient Safety & Quality Healthcare* 7:1, 26-30, Jan-Feb 2010.
- Arney D, Goldman JM, Whitehead SF, Lee I, "Synchronizing an X-ray and Anesthesia Machine Ventilator: A Medical Device Interoperability Case Study", *Proceedings of BioDevices 2009*.
- Arney D, Pajic M, Goldman JM, Lee I, Mangharam R, Sokolsky O, "Toward Patient Safety in Closed-Loop Medical Device Systems," In: *Proceedings of International Conference on Cyber Physical Systems*, April 2010.

Funding Applications Facilitated by this BAA to Date (total costs shown):

- Funded: CIMIT: \$51K for FY10 program leader support
- Funded: CIMIT: \$51K for FY11 program leader support
- Funded: CIMIT: \$98K for FY11 support for development of a pre-clinical PCA closed-loop control application
- Funded: CIMIT: \$98K for FY11 support for interoperability of portable x-ray devices with ventilators in an ICU at a VA hospital (collaboration with VA Boston)
- Funded: CIMIT: \$98K for FY11 support for development of a clinical algorithm-driven interoperable smart ventilator (collaboration with Boston University)
- Funded: TATRC: \$70K for MD PnP subcontract on Moberg Research SBIR Phase II award
- Funded: TATRC: \$100K for MD PnP subcontract on DocBox Inc. award
- Funded: NSF: \$620K for MGH subcontract on University of Pennsylvania 5-year award
- Funded: NIBIB: \$9.9M for 5-year development of prototype healthcare intranet, an open ICE platform

Other: In-kind engineering support and/or contribution of equipment for the lab from Draeger Medical, Philips Healthcare, FDA, Draper Laboratory, Kaiser Permanente, University of Pennsylvania, LiveData Inc., and DocBox Inc. (valued at approximately \$500,000 to date). Lockheed Martin joined CIMIT's Industry Liaison Program in order to work with CIMIT and the MD PnP program, and has provided \$100K of equipment to run and display their virtual clinical environments prototype.

Conclusions

As with prior TATRC BAA support, this BAA has provided core program support that enables the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program to provide key clinically focused leadership of the growing move towards open standards and related technologies for networking medical devices to support clinical solutions for improving patient safety and healthcare efficiency. The majority of this BAA has been used for core personnel salary support, which provides the foundation to identify and access other available resources, to lead relevant standards work, and to build collaborations to achieve device interoperability objectives. These collaborations include activities and relationships with federal agencies and the White House; clinical, engineering, and IT societies; clinicians in the US, Canada, Europe, and Japan; and integrated healthcare delivery organizations like Kaiser Permanente, Johns Hopkins, Partners HealthCare, and the Veterans Health Administration.

Although we have been successful in the past year in attracting funding from several federal agencies (NIH, NSF, NIST), as well as CIMIT, all of this funding is project-specific and does not support the standards work, convening, and relationship-building that the TATRC funding has so greatly enhanced.

Notable achievements enabled or facilitated by this TATRC support include:

- We led the development of an international standard for the Integrated Clinical Environment (ICE) and saw it through to adoption and publication by ASTM International;
- Three major healthcare delivery systems collaborated on shared interoperability contracting language under MD PnP program leadership, and this language is now in a second iteration being reviewed by the VA;
- Seven medical societies (including the AMA) have endorsed the need for medical device interoperability;
- Strong collaborations have been established with the Veterans Administration and with federal agencies, including the Office of the National Coordinator for Health IT and the White House, putting medical device interoperability on the national healthcare agenda
- The FDA held a jointly sponsored Workshop on Medical Device Interoperability and is now working with industry and our program on a prototype regulatory submission of a system of integrated medical devices

These activities are highly interdependent and synergistic, and TATRC support has been instrumental in providing the "program glue" to effectively leverage these synergies to realize our mutual program objectives.

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Appendices

Agenda for FDA Workshop on Medical Device Interoperability – January 2010
 MD PnP article in Jan-Feb 2010 issue of *Patient Safety & Quality Healthcare*
INCOSE Insight article on Dr. Goldman's keynote address
 Abstract from NIH NIBIB Quantum grant

Workshop on Medical Device Interoperability: *Achieving Safety and Effectiveness*

Co-Sponsored by
FDA/CDRH, Continua Health Alliance,
and CIMIT

FDA White Oak Campus
10903 New Hampshire Ave.
Silver Spring, MD 20993

January 25-27, 2010

Updated workshop information is available at:
http://mdpnp.org/FDA_Interop_Workshop.php

Final Workshop Agenda

INTRODUCTION

Over the past two decades, advances in computing technology have brought many benefits to the US marketplace; similar trends are seen globally. The advances in computing technology have influenced communication (cell phones, email, social media networks), information availability (web 2.0), and consumer expectations. The technology trends include an increase in computational horsepower coupled with a decrease in component size, cost of memory, and power consumption. These advances and expectations are experienced by medical device users and patients. More recently, computational and network technology and the Internet have extended their reach to virtually every medical device that can benefit from the ability to share information. These technology trends are enabling expanded feature sets, allowing diagnostic and therapeutic equipment to be tailored to a range of specialized clinical situations, home care, and portable applications. Devices ranging from personal health devices to high acuity clinical care systems can benefit from integration.

On the other hand, there is a hidden cost to many of these benefits: the challenge of managing ever-increasing complexity in the design and use of medical devices. A significant effort on the part of FDA scientists and engineers is to understand and explore the safety implications of this emerging complexity to assure public health. We recognize that improved product designs are the key to reducing adverse events (for example, via automated interlocks) and enabling new clinical treatments that are greater than the sum of their components. This workshop is a joint effort between FDA/CDRH, and external technology and clinical partners, the Continua Health Alliance, and the Center for Integration of Medicine and Innovative Technology (CIMIT) to explore representative use cases describing interoperable “systems of systems.” The intent of the exploration is to identify potentially hazardous scenarios that arise from these systems and discuss potential solutions for assuring their safety and effectiveness.

Attendees are invited to fully participate in this workshop. We have organized this agenda to facilitate constructive interactions among all attendees with the express purpose of eliciting useful and novel ideas and proposals. Our goal is to help identify potential methods to assure safe, effective, and least burdensome solutions for interoperable medical devices that benefit manufacturers, payors, providers, and most importantly consumers and patients.

The flow of the conference is intended to highlight the various dimensions of the challenges of interoperability. The opening sessions describe both the need for interoperability and the complexity of the problem. The presentations are meant to highlight the various contexts, environments, and applications for interoperable medical devices. Workgroups have been planned so that particular issues can be explored deeply.

We look forward to a productive and simulating workshop.

Workshop Steering and Organizing Committee Co-Chairs:

Julian M. Goldman, MD	Partners HealthCare / CIMIT
John Murray	FDA
Michael Robkin	Anakena Solutions
Scott Thiel, MBA, RAC	Roche Diagnostics
Sandy Weininger, PhD	FDA

Please note: To access the video of specific workshop talks, click on the link provided in the agenda for each talk. When the video window opens, go to the “Playing” bar at the bottom of the screen and move the vertical bar to the right to align it with the timestamp for that talk. *Do not use Advanced Options.*

Day 1: Monday, January 25, 2010, Morning Session

8:00 – 9:00 **CONTINENTAL BREAKFAST**

9:00 – 9:20 **OPENING, LOGISTICS, WELCOME**

Donna-Bea Tillman, PhD

Director, Office of Device Evaluation, FDA/CDRH

<https://collaboration.fda.gov/p57306401/> [0:1:40]

9:20 – 10:00 **Device interoperability and the National Health IT Agenda**

Charles P. Friedman, PhD.

Chief Scientific Officer,

Office of the National Coordinator for Health IT

<https://collaboration.fda.gov/p57306401/> [0:11:20]

10:00 – 10:30 **Safety and Effectiveness Challenges in Interoperability**

The challenges of managing the complexity of interoperable systems. The national perspective on interoperability in health care delivery.

Jeff Shuren, MD, JD

Director, FDA/CDRH

<https://collaboration.fda.gov/p57306401/> [1:04:49]

10:30 – 10:50 **Setting the Stage: Device, Local, Regional, and National Perspectives on Medical Device Interoperability**

Medical device interoperability can range from the device-to-device interactions around a patient through the exchange of information across disparate public and private sector enterprises.

Doug Rosendale, D.O. F.A.C.O.S

Veterans Health Administration, Office of Health Information,
Joint Interoperability Ventures;

Doctor of Osteopathic Medicine and Fellow of the American
College of Osteopathic Surgeons

<https://collaboration.fda.gov/p57306401/> [1:17:28]

10:50 – 11:20 **BREAK**

11:20 – 11:40 **Clinical Perspective on Interoperable Medical Device Systems**

Medical device interoperability could enable the integration of devices and IT systems in clinical environments. This integration holds great promise for improving the safety and efficiency of health care delivery.

Julian M. Goldman, MD

Director, MD PnP Program and CIMT Program on Interoperability

Medical Director, Partners HealthCare Biomedical Engineering

Attending Anesthesiologist, Massachusetts General

Hospital/Harvard Medical School

<https://collaboration.fda.gov/p57306401/> [2:25:00]

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11:40 – 12:00

Consumer and Patient Perspective on Innovation and Interoperability in Healthcare

What happens when a technology guy becomes a patient? Or why can't healthcare innovate as fast as the rest of the economy?

Dave deBronkart

"e-Patient Dave", e-patients.net; Co-Chair, Society for Participatory Medicine

<https://collaboration.fda.gov/p57306401/> [3:02:57]

12:00 – 1:00

LUNCH

Day 1: Monday, January 25, 2010 Afternoon Session

1:00 – 1:10

Introduction to Presentations

Presentations highlighting a particular use scenario that shows medical devices acting in an interoperable manner to achieve an intended use will be used to explore safety and effectiveness issues and possible solutions. Presentations related by content have been organized into thematic sessions as indicated below.

Each presentation will consist of a short (5 minute) description of a particular use case or scenario involving interoperable medical devices, a description of the inherent regulatory or safety issues, stakeholders and how they are affected, and proposed solutions. Each group of presentations will be followed by 20 minutes of moderated panel and audience Q&A.

1:10 – 1:50

Session 1: Lessons Learned from Existing Regulatory Practices

<https://collaboration.fda.gov/p89529623/> [0:13:48]

Moderator	Brad Thompson	Partner	Epstein Becker Green
NHS	Maureen Baker CBE	Clinical Director of Patient Safety	NHS Connecting for Health, England
Diabetes and Home Management	Yi Zhang	Visiting Scientist	CDRH/OSEL/DESE
FDA	Mary Brady	Associate Office Director	FDA/CDRH/OSB Home Care Initiatives

1:50 – 2:30

Session 2: Enterprise Issues

<https://collaboration.fda.gov/p89529623/> [1:01:45]

Moderator	Michael Robkin	President	Anakena Solutions
Digital Operating Room	Tom Judd	National Project Director, Clinical Technology	Kaiser Foundation Hospitals
	Tom McGrane	Principal Solution Consultant	Kaiser Foundation Hospitals
	Doug Grey, MD	Chair, KP Biomedical Device Integration Council Vice-Chair, KP National Product Council	The Permanente Medical Group

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Converged Medical Device and Enterprise Network	Tim Gee	Principal	Medical Connectivity Consulting
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2:30 – 2:50 BREAK

2:50 – 3:30 Session 3: Systems-of-Systems Issues

<https://collaboration.fda.gov/p89529623/> [2:01:56]

Moderator	Julian M. Goldman, MD	Physician	MGH/PHS/ CIMIT
Systems of Systems Issues	Frank E. Block, Jr., MD	Professor of Anesthesiology	Virginia Commonwealth University
Using Standard Communications Protocols to Implement Medical Device Plug-and-Play	Dick Moberg	President	Moberg Research, Inc.
Wrangling the human element of interoperability: Defending against Reason's latent flaws and Dekker's drift	GM Samaras, PhD, DSc, PE, CPE, CQE	CEO	Samaras & Associates, Inc

3:30 – 4:10 Session 4: Mass Interoperability

<https://collaboration.fda.gov/p89529623/> [2:47:40]

Moderator	Brad Thompson	Partner	Epstein Becker Green
Mobile Health	Praduman Jain	CEO	Vignet Inc.
"Tooling" Communities to Advance Community Resilience	Dr. Brigitte Pinewski	CMO	PeaceHealth Labs
The Do's and Don'ts of Creating an ULP Wireless Network	Mike Paradis	Wireless Sales Manager	Dynastream Innovations Inc.

4:10 – 4:50 Session 5: System Level Risk Analysis

<https://collaboration.fda.gov/p89529623/> [3:25:35]

Moderator	Brian Fitzgerald	Deputy Director	Center for Division of Electronic and Software Engineering; Office of Science and Engineering Labs; CDRH/FDA
Multi-parameter data integration to support clinical decision making	John Zaleski, PhD, CPHIMS	Department Head, Biomedical Informatics	Philips Research North America
FiO2 Control in Preterm Infants – A Case for Device Interoperability	Dale Wiggins	Vice President and CTO Healthcare Informatics and Patient Monitoring	Philips Healthcare
The Building Blocks of Clinical Systems	Tracy Rausch	Founder and CTO	DocBox Inc
Managing Risk in Systems of Systems	Peter Kelley	Director of QA/RA	Capsule Technology Inc

Final Workshop Agenda

4:50 – 5:00 **Day 1 Closing Session**
6:00 – 8:00 **Reception at Sheraton Washington North Hotel**
 Sponsored by the Continua Health Alliance

Day 2: Tuesday, January 26, 2010 Morning Session

8:00 – 9:00 **CONTINENTAL BREAKFAST**

9:00 – 9:20 **A Short History of Interoperability**
Current technical solutions and perspectives for interoperability.
Advantages and pitfalls of design patterns such as Systems of Systems (ICE), Peer-to-Peer (point-to-point standards), Various Industry perspective and approaches to interoperability.

Michael Robkin
President, Consultant
Anakena Solutions
<https://collaboration.fda.gov/p25617965/> [0:03:30]

9:20 – 9:40 **Pieces of the Puzzle: Actors in Interoperability**
Many organizations have a role to play in assuring the safety and effectiveness of interoperable medical devices. Many stakeholders and industry segments have to come together to achieve interoperability. Who is involved and what pieces have to come together to create workable solutions to the problem. Consequences for standards bodies, test houses, end users, regulated manufacturers, hospitals, clinicians, consumers, commercial manufacturers.

Sandy Weininger, PhD
Senior Biomedical Engineer
FDA/CDRH/Office of Science and Engineering
<https://collaboration.fda.gov/p25617965/> [0:28:50]

9:40 – 10:00 **Making it Happen: Manufacturer Perspectives on Medical Device Interoperability**
What are the issues that a manufacturer must address throughout a product's lifecycle as a result of interoperable medical devices. What solutions are practical for both regulated and non-regulated manufacturers.

Scott Thiel, MBA, MT (ASCP), RAC
Roche Diagnostics
Global Regulatory Affairs Diabetes Care
Regulatory Affairs Program Manager
<https://collaboration.fda.gov/p25617965/> [0:49:00]

10:00 – 10:20 **BREAK**

Final Workshop Agenda

10:20 – 11:00 Sessions 6: Software Issues

<https://collaboration.fda.gov/p25617965/> [1:37:20]

Moderator	Rick Schrenker	Systems Manager, Biomedical Engineering	Massachusetts General Hospital
Safety and Effectiveness Issues in Electronic Medical Records	John Denning	Consultant	Independent
Medical Device Data Patient Context Challenges	Luis Melendez	Assistant Director, Partners HealthCare Biomedical Engineering, Medical Device Integration and Informatics	Massachusetts General Hospital

11:00 – 11:40 Session 7: Integration and Interoperability Issues in a Regulated Environment

<https://collaboration.fda.gov/p25617965/> [2:21:50]

Moderator	Scott Thiel	Chair, Regulatory Working Group; Regulatory Affairs Program Manager	Continua Roche
Interoperability through integration	Renate A. MacLaren, PhD	Director, Regulatory Affairs	Integrated Medical Systems, Inc.
Universal interface between medical devices and IT / Communications systems	Alasdair MacDonald	CEO	TeleMedic Systems Ltd
Toward a plug-and-play system for medical devices: lessons from case studies	Dave Arney	Doctoral Candidate	University of Pennsylvania

11:40 – 12:20 Session 8: Standards, Interfaces and Interoperability Issues

<https://collaboration.fda.gov/p25617965/> [2:58:20]

Moderator	Dave Osborn	Manager, International Standards, Standards & Regulations Department	Philips Medical Systems
Impact of ARRA/HITECH on Device Connectivity: Safe? Effective? Say what?!	Todd Cooper	President	Breakthrough Solutions Foundry, Inc.
Connectivity? Integration? Plug and Play? What is the Interoperability end game?	Ken Fuchs	Principal Engineer	Draeger Medical Systems, Inc.
Semantic Interoperability for Medical Device Data Interchange	Paul Schluter, PhD	Principal Engineer	GE Healthcare Monitoring Solutions
Helping the Cause of Medical Device Interoperability through Standards-based Test Tools	John J. Garguilo	Computer Scientist	NIST
ICE-PAC Approach to Understanding Clinical Requirements	Tracy Rausch	Founder and CTO	DocBox Inc

12:20 – 1:00 LUNCH

Day 2: Tuesday, January 26, 2010 Afternoon Session

1:00 – 1:10 Introduction to Breakout Working Sessions #1
These breakout sessions provide time to discuss the issues raised in the scenario presentations in more detail. They are organized first by stakeholder responsibility and then by technical expertise. Final group structure will be determined based on registration.

1:20 – 2:20 Breakout Working Sessions #1 (concurrent)

- Discovered issues (criticality, priority)
- Proposed solutions (gaps, implementation issues, dependencies with other factors, guidance document content)

High Acuity Regulated Manufacturer Breakout Session
<https://collaboration.fda.gov/p98311968/> [0:07:20] (first part)
<https://collaboration.fda.gov/p46885825/> [0:00:00] (second part)

Low Acuity Breakout Session
<https://collaboration.fda.gov/p43609764/> [0:00:00]

Hospital/Provider Breakout Session
<https://collaboration.fda.gov/p28243961/> [0:00:00]

Research Policy Breakout Session
<https://collaboration.fda.gov/p14916895/> [0:00:00]

Infrastructure Breakout Session
<https://collaboration.fda.gov/p76954099/> [0:00:00]

3:20 – 3:40 BREAK

3:20 – 3:30 Introduction to Breakout Working Sessions #2
Description and rationale for separation by problem domain.

3:30 – 4:30 Breakout Working Sessions #2 (concurrent)

- Discovered issues (criticality, priority)
- Proposed solutions (gaps, implementation issues, dependencies with other factors, guidance document content)

High Acuity Regulated Manufacturer Second Breakout Session
<https://collaboration.fda.gov/p79789115/> [0:00:00]

Low Acuity Second Breakout Session
<https://collaboration.fda.gov/p16937097/> [0:00:00]

Hospital/Provider Second Breakout Session
<https://collaboration.fda.gov/p20943231/> [0:00:00]

Medical Device Interoperability Workshop

FDA White Oak – January 25-27, 2010

Final Workshop Agenda

Research Policy Second Breakout Session

<https://collaboration.fda.gov/p67463150/> [0:00:00]

Infrastructure Second Breakout Session

<https://collaboration.fda.gov/p44245561/> [0:00:00]

Day 3: Wednesday, January 27, 2010 Morning Session

8:00 – 9:00	Continental Breakfast
9:00 – 9:10	Housekeeping https://collaboration.fda.gov/p93981535/ [0:00:00]
9:10 – 10:15	Breakout Sessions Report Back https://collaboration.fda.gov/p93981535/ [0:06:10]
10:15 – 10:45	FDA Report Back https://collaboration.fda.gov/p93981535/ [1:21:45]
10:45 – 11:15	Q&A: When is my smartphone a medical device? John Murray Brad Thompson https://collaboration.fda.gov/p93981535/ [1:41:00]
11:15 – 11:30	UDI Q&A https://collaboration.fda.gov/p93981535/ [2:11:00]
11:30 – 11:45	Organizing Committee Wrap Up https://collaboration.fda.gov/p93981535/ [2:31:00]
11:45	ADJOURNMENT

Slides:

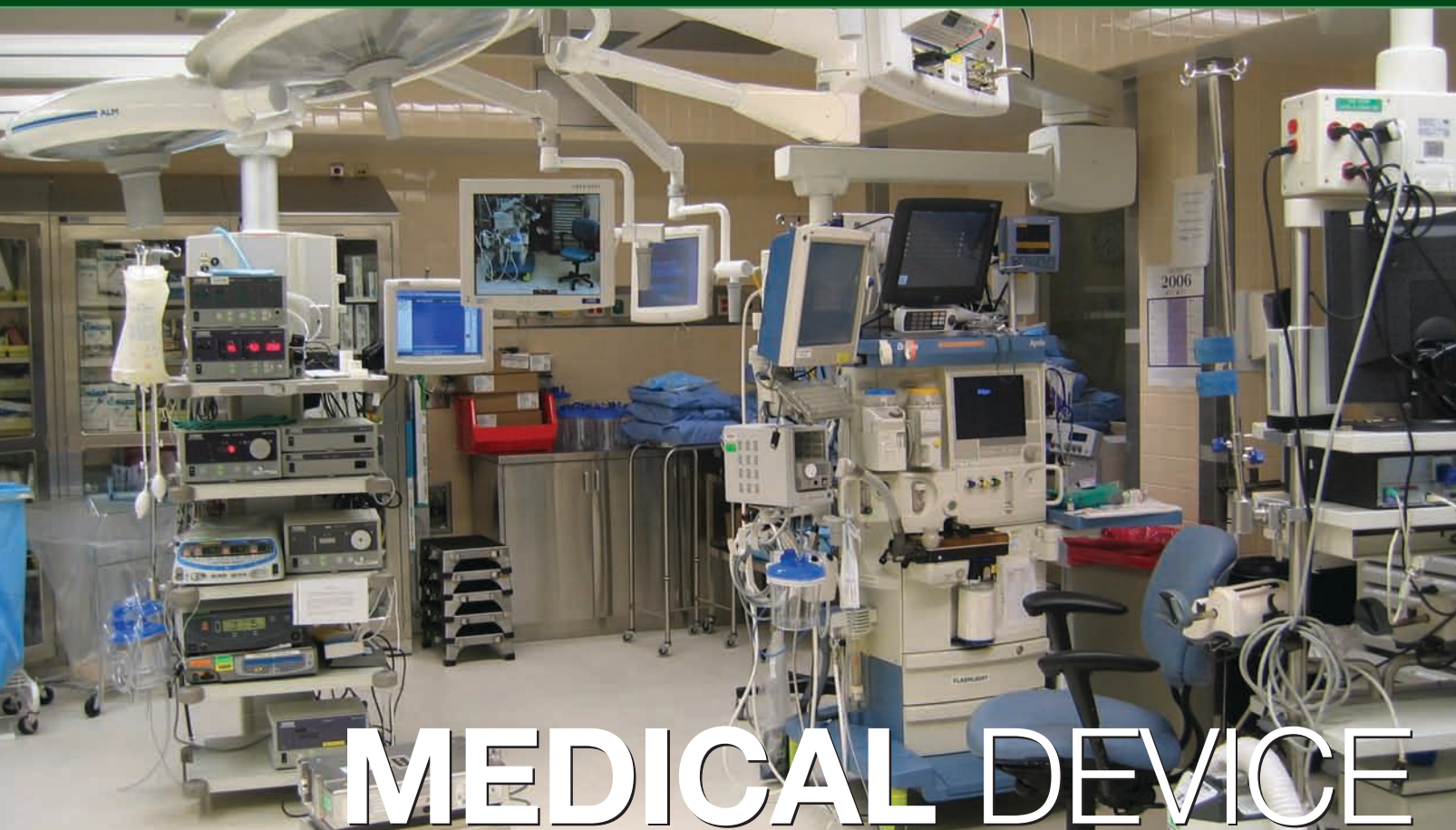
http://mdpnp.org/FDA_Workshop_Slides.php

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MEDICAL DEVICE INTEROPERABILITY

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Connectivity to Improve Patient Safety

Making Medical Device “Plug-and-Play” Interoperability a Reality

By
Susan F. Whitehead and
Julian M. Goldman, MD

In

previous *PSQH* articles (2008, 2009) we have described the importance of medical device interoperability for improving patient safety, and have

reported on the growing support of clinicians and healthcare delivery organizations to have access to this capability. For the past 5 years the Medical Device “Plug-and-Play” (MD PnP) Interoperability Program has been leading the evaluation and adoption of open standards and technology for medical device interoperability to support clinical innovation and improve patient safety. Now we are pleased to report that there has been significant national progress towards that goal.

Why is achieving medical device interoperability important? Improvements in patient safety, clinical care, and healthcare efficiency require systems solutions. Medical devices and information systems in high-acuity clinical environments must be easily integrated to enable the creation of smarter, error-resistant systems. The adoption of open standards for medical device interoperability will support:

- Complete, accurate electronic medical record systems (EMRS)
- Reduction of errors caused by manually entered data
- Facilitation of disaster preparedness: real-time inventory of hospital equipment in use and in national stockpiles
- Rapid deployment of devices in makeshift emergency care settings
- Medical device safety interlocks to produce error-resistant systems
- Clinical decision support systems and smart clinical alarms (with context-awareness)



Image courtesy of Julian Goldman, MD

- Support of remote healthcare delivery
- Automated system readiness assessment (prior to starting invasive clinical procedures)
- Reduction of cost of devices and device integration, and reduction of accelerating EMR-adoption costs
- Closed-loop control of therapeutic devices and safety interlocks (e.g. ventilation, medication and fluid delivery)

Getting there is not easy. There is an inherent “chicken and egg” problem. We cannot simply specify standards like “USB 2.0 compliance,” as we can when purchasing computers, because interoperability standards have not been adopted. Existing standards for non-high-acuity device communication are not likely to be capable of supporting the necessary clinical use cases or clinical workflow scenarios in high-acuity healthcare. Therefore, it is essential to assess candidate interface standards to inform the required changes in existing standards, and to develop additional standards if needed.

The paradox continues: Since development of the necessary open standards and technology requires significant resources, there has been reluctance to pursue these solutions without demonstration of clinical benefit. But the implementation of technology to integrate disparate medical devices and IT systems is a necessary step to demonstrate clinical benefit. A rational way to circumvent this impasse, and solve a few related problems, is to develop an open interoperability platform, to help define the safety and technology requirements of the new systems that will be built, and to better understand the safety and performance requirements of hardware and software in these new “systems of systems” environments. The complexity of this challenge requires that we work on all of these multiple facets simultaneously (standards, clinical pull, funding sources, use case demonstrations, open platform development), while also addressing regulatory concerns. These are the challenges that the MD PnP program has been addressing since 2004.

The MD PnP program is affiliated with Massachusetts General Hospital (MGH), CIMIT (Center for Integration of Medicine and Innovative Technology), and Partners HealthCare Information Systems, with additional direct support from TATRC (U.S. Army Telemedicine & Advanced Technology Research Center). Having evolved from the OR of the Future program at MGH, the MD PnP program remains clinically grounded, in contrast to “technology push” interoperability-related efforts. From its docking point within CIMIT, MD PnP has harnessed organizational skills in convening and facilitation to involve diverse stakeholder groups (clinicians, biomedical and clinical engineers, healthcare delivery organizations, regulatory agencies, medical device vendors, and standards development experts). The MD PnP program has built a geographically dispersed, interdisciplinary, multi-institutional team that is developing strategy and building blocks for device interoperability through collaborative projects. Since the program’s inception, more than 700 clinical and engineering experts, and representatives of more than 90 institutions that

share a vision of medical device interoperability have participated in MD PnP activities.

MD PnP program activities have included (1) convening five plenary meetings and many smaller workgroups to bring stakeholders together for information exchange and discussion of issues related to adopting medical device interoperability, (2) developing a methodology for defining clinical requirements, eliciting and collecting high-level clinical scenarios that would benefit from medical device interoperability, and making these use cases available to collaborative projects, (3) developing the MD PnP Lab (in Cambridge, MA) as a vendor-neutral “sandbox” for interoperability and standards conformance testing, collaborative development of use case demonstrations, and development of sharable tools and resources for medical device interoperability work, (4) facilitating medical societies and healthcare delivery organizations to endorse and demand medical device interoperability, (5) developing scientific exhibits to show how interoperability could improve patient safety in typical clinical scenarios, and demonstrating these at national conferences, (6) working with academia, industry, and federal agencies on projects to ensure safe implementation of device interoperability and to instantiate the concepts, and (7) keeping medical devices in the picture for the national health IT agenda.

Over the past 5 years, the focus and work of the MD PnP program has evolved into five interdependent and synergistic themes, being pursued in parallel:

- Standards Development
- Open Platform Development
- Clinical and Engineering Requirements for Device Interoperability
- Facilitated Collaboration
- Regulatory Pathway

Standards Development

The MD PnP program has been contributing leadership, clinical requirements, and technical expertise to standards development organizations that are developing interoperability-enabling standards (e.g. ASTM International, ISO, and IEEE). Most recently, we contributed content to the ASTM ICE standard (see below) and to Technical Note 905 for the HITSP (Healthcare Information Technology Standards Panel) Common Device Connectivity Extension/Gap, which seeks to define requirements for more tightly integrating medical devices into EMRS.

ICE Standard. Establishing a high-acuity standards framework began with a standard for an “Integrated Clinical Environment” (ICE) to define the requirements for interoperability to successfully improve patient safety and clinical workflow. A multi-institutional writing group convened by ASTM International with MD PnP leadership—including engineers and standards experts—drafted Part I of the multi-part ICE standard that embodies the elements of the overall technology ecosystem to safely implement networked medical device systems. This draft was submitted by ASTM as a New Work Item Proposal to the IEC/ISO international standards development organiza-

tions in late 2007. It received a tie vote in ISO, which was insufficient for adoption as a New Work Item.

Comments (over 120) submitted during the ISO/IEC review process revealed strong support from clinical institutions, gaps in the technical and clinical content, and specious criticism from organizations with proprietary interests. An FDA-hosted meeting with regulatory, technical, and standards experts was instrumental in allaying misconceptions and enhancing mutual understanding, to the benefit of the ICE standard. Submitted comments were systematically reviewed and addressed by ASTM, resulting in a greatly improved draft standard: “Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE).” Part I was re-scoped and re-named “General requirements and conceptual model,” and it delineates more specific ICE parts (to be written). ICE Part I was published by ASTM as F2761-2009 in December 2009, and is available on the ASTM website.

Open Platform Development

To date we have used the MD PnP Lab to develop demonstration implementations of clinical use cases in which integrating the clinical environment will improve patient safety; these use case implementations have been shown at major clinical and health IT conferences. Now we must build an open interoperability platform and define safety and technology requirements for the interoperability systems that will be built (these can be considered “systems of systems”). This must be a comprehensive platform—analogue to the Internet—that will allow the global community to build innovative clinical applications on top of it. With CIMIT funding we have been working on the first instantiation of an open mobile platform for clinical delivery of evolving MD PnP functionality. This hardware and software platform is intended to support iterative development of MD PnP standards (e.g. ICE) and related technologies for external collaboration.

Use Case Implementation. Our first use case demonstration, presented at the 2007 American Society of Anesthesiologists (ASA) meeting and the 2007 CIMIT Innovation Congress, showed how automatic synchronization of x-ray exposure with ventilation could enable clear images to be obtained without the need to turn off the ventilator—a straightforward application of integrated medical devices that is still not commercially available 10 years after the technical solution was demonstrated and published. Our second demonstration addressed a patient safety issue that has been the cause of many adverse events; we showed an error-resistant patient-controlled analgesia (PCA) medication delivery system with safety interlocks to prevent overdose, based on PCA / monitor interoperability—this scientific exhibit was recognized with a first place award at the 2008 ASA annual meeting.

The initial prototype implementation of the mobile platform is based on the PCA use case and provides the preliminary foundation for an open research platform that could support evaluations by the FDA of MD PnP systems and serve as a generic platform that could be shared with other organizations developing, for example, open medical device interface

adapters and an ICE Part I reference architecture. Over several iterations, our multi-institutional development team (engineers from three universities in three countries: the University of Pennsylvania, the University of Waterloo, Canada, and the University of Applied Science, Wiener-Neustadt, Austria), implemented a “medical network” capability and developed “device interface boards” to provide an initial model of what could be used for an open ICE platform; this implementation was exhibited at HIMSS08 (Healthcare Information & Management Systems Society). For HIMSS09 the team developed a tabletop version of the system with enhanced and miniaturized PnP adapters, and added a basic “black box data recorder” capability (also required by ICE).

In scientific exhibits at HIMSS08, HIMSS09, 2008 CIMIT Innovation Congress, and ATA09 (American Telemedicine Association), we demonstrated how continuous monitoring of the patient’s SpO₂ and respiratory rate could detect the onset of respiratory depression, and how integration of the PCA pump and monitors can automatically stop the infusion, lock out further doses, and activate the nurse call system. The exhibit demonstrated that the plug-and-play capability to easily swap different monitors to assess respiratory function could increase the reliability of problem detection (increase sensitivity) while reducing false alarms. The exhibit attracted considerable interest from medical device companies and other visitors.

Clinical and Engineering Requirements for Device Interoperability

The need to start with clinical requirements was identified early by all stakeholder groups as critical to the creation of a clinically valid standardization framework. To gather these clinical requirements, we have held focus group sessions at medical and engineering society meetings; participants have included anesthesiologists (Society for Technology in Anesthesia, and ASA), surgeons (Society of American Gastrointestinal Endoscopic Surgeons), and clinical and biomedical engineers (Association of Advanced Medical Instrumentation). Each of these groups brought unique perspectives on what interoperability of medical devices could contribute to patient safety and workflow efficiency, and on how the “ideal” system should look and behave.

The raw input from focus group sessions was organized into defined clinical scenarios or “use cases,” which were presented back to earlier domain experts for refinement. Several clinical scenarios were incorporated into the ICE Part I standard, and a team of MD PnP collaborators (called the ICE-PAC) has been performing detailed workflow analysis of these use cases and analyzing the ability of the IEEE 11073 set of standards to meet these requirements. Collaborators working on ICE-related development projects (see **Facilitated Collaboration** below) have an ongoing need for additional high-level clinical scenarios to be developed into detailed clinical workflows and then into requirements.

Society endorsements. Beginning in March 2007, the need for medical device interoperability has been endorsed by seven clinical societies to date—the Anesthesia Patient Safety Foun-

dation, the American Society of Anesthesiologists, the Society of American Gastrointestinal Endoscopic Surgeons, the World Federation of Societies of Anaesthesiologists, the Society for Technology in Anesthesia, and most recently the American Medical Association and the Massachusetts Medical Society:

RESOLVED, That our American Medical Association (AMA) believes that intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind. Our AMA also recognizes that, as in all technological advances, interoperability poses safety and medico-legal challenges as well. The development of standards and production of interoperable equipment protocols should strike the proper balance to achieve optimum patient safety, efficiency, and outcome benefit while preserving incentives to ensure continuing innovation.

Healthcare Delivery Organizations. As a result of collaboration with the MD PnP program, Kaiser Permanente in 2006 began to include limited requirements for medical device interoperability in vendor contracts. Under the leadership of the MD PnP program, two additional major Healthcare Delivery Organizations (HDOs)—MGH / Partners HealthCare and Johns Hopkins Medicine—became actively engaged in this effort in 2008 with the goal of expanding and strengthening the original language to make it clear that customers want this capability and expect vendors to cooperate in making it happen. In October 2008 these institutions issued a nationwide Call to Action to HDOs to improve patient safety by recommending that medical device interoperability requirements be included as an essential element in vendor selection criteria and procurement processes. This collaboration produced sample RFP and contracting language that is being shared with other institutions as well as device manufacturers (MD FIRE: Medical Device Free Interoperability Requirements for the Enterprise) and is available through our program website. MD FIRE was presented in a March 2009 webcast at the VHA (Volunteer Hospital Association), heard by more than 140 hospitals. Recently, the U.K. National Health Service has used the MD FIRE document for HIT system requirements.

Facilitated Collaboration

Convening diverse stakeholders and maintaining their engagement has been a key focus of the MD PnP program and is a good fit with the mission of our home in CIMIT. To date we have convened five plenary meetings (with TATRC, CIMIT, NSF, and FDA sponsorship) to bring stakeholders together for information exchange and discussion of issues related to achieving medical device interoperability. The kick-off meeting in May 2004 solidified interest and support across stakeholder groups to pursue standards for medical device interoperability. The FDA hosted the second meeting in November 2004, so that regulatory issues could be more thoroughly explored with increased FDA partici-

pation. At a third plenary meeting in June 2005 stakeholders began to frame the issues around eliciting and defining clinical requirements for interoperability, and they identified useful functionality for a shared “sandbox” laboratory for prototype development and testing against proposed standards.

A Joint HCMDSS (High Confidence Medical Devices, Software, and Systems)/MD PnP Workshop held in June 2007, which added academic embedded-systems experts to interact with stakeholders, attracted 145 attendees. This workshop brought together two highly synergistic research communities (MD PnP and HCMDSS), included a panel of federal agencies interested in interoperability (NIST (National Institute of Standards & Technology), NSF, NIH, TATRC, FDA), and had as the opening keynote speaker Dr. Robert Kolodner, then National Coordinator for Health IT, generating a more solid connection with the national health IT agenda.

The program has convened smaller working group meetings to develop program strategy, to work on methodology, to develop MD PnP demonstrations, and to draft the ICE standard. In July 2009 the MD PnP program convened 40 invited participants from organizations that are working collaboratively on funded projects to research development and safety issues in implementation of safe and effective networks of integrated medical devices (systems of systems). In addition to meetings, our website (<http://www.mdnp.org/>) provides extensive information about the program, including streaming video of the talks from the May 2004, June 2005, and June 2007 meetings. We have been gratified that medical device interoperability has become part of the national HIT dialogue.

The interest of DoD in advancing medical device interoperability has been demonstrated by six awarded small business research grants for device interoperability-related development, including ICE Manager capabilities and ICE Supervisor functionality for trauma assistance. These projects are producing products and technology that will inform the future development and architecture of an open ICE development platform, as well as subsequent parts of the ICE standard.

In addition, collaborative work that is currently underway with two university computer science and engineering groups (University of Pennsylvania and University of Illinois at Urbana-Champaign) is expected to inform both the ICE standard and the ICE development platform. For example, a graduate student from Urbana-Champaign spent the summer of 2008 as an intern at the FDA, working with senior technical staff involved in the MD PnP program. He focused on safety modeling and analysis for interoperable medical device systems.

ICE-PIC. Over the 2 years since our last major plenary meeting in June 2007, the MD PnP program has formed collaborations with academic groups funded by NSF and with companies funded by DoD small business research grants to work on projects related to medical device interoperability and to the ICE standard in particular. Collaborative relationships with federal agencies have grown, and now include TATRC, FDA, NSF, NIST, and the Veterans Administration. There has been extensive work on developing the ICE standard, and the ICE-PAC gap analysis

is underway, including participation by several device manufacturers. In order to facilitate synergistic progress and accelerate our mutual objectives, the MD PnP program organized a 2-day workshop of these collaborators (called the ICE-PIC—ICE Platform Integration Collaboration) in July 2009.

The 40 invited participants represented four universities, three healthcare delivery systems, nine companies, and three federal agencies. They included clinical users, biomedical engineers, information systems engineers, federal regulators, program managers, medical device manufacturers, and standards experts. They presented their project work, shared their vision and ideas, and worked together on a plan for future collaborative activities to advance the ICE standard and development of an open ICE research platform. Several members of this group are participating in the further development of the ICE standard.

Regulatory Pathway

An early premise of the MD PnP program has been that the goal of medical device interoperability standardization can only be achieved by working closely with the FDA, and this has been the approach to date. The mutual objective of the FDA and the MD PnP program leaders is to identify a regulatory pathway that will support the MD PnP concept, i.e. which will support safe integration of devices and not require re-validation or re-clearance of the entire system as each new independently validated device is added to the MD PnP network. Over the past 4 years we have studied and elaborated the issues and concerns surfaced by medical device interoperability stakeholders, and have increased the community's understanding of them. We are continuing to pursue opportunities to work with the FDA in standards development activities, in discussions of the solution pathway offered by ICE, and on projects with our collaborators involving safety studies.

MD PnP is collaborating with the FDA and the Continua Health Alliance to co-sponsor and plan a workshop on medical device interoperability to be held at FDA in January 2010. This workshop, which is expected to attract 200 participants, will focus on recent and future efforts to establish safe and effective medical device interoperability and the probable impact on regulations and policies. The workshop will include device industry, clinical, academic, and FDA perspectives, and is intended to enable FDA to collect community input to develop regulatory guidance for interoperability for healthcare. (Workshop information at http://mdpnp.org/FDA_Interop_Workshop.php)

What Is Needed for Success?

In order to develop and achieve adoption of a standardization framework for medical device interoperability that has the support and buy-in of all stakeholders, we need clinically meaningful use cases and requirements, published open interoperability standards to enable meaningful use cases, an open development platform to provide enabling technology, reference implementations of the standards and related system architecture, profiles or guidelines to describe how to use the standards to achieve interoperability, a vendor-neutral compliance testing and evaluation environment, interoperability and conformance testing tools,

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strongly articulated user demand, a staged implementation plan that recognizes the need to accommodate legacy systems, and an appropriate regulatory pathway.

As an independent, vendor-neutral program, the MD PnP program is acting as the catalyst to bring the full spectrum of stakeholders together to achieve the goal of medical device interoperability. Over the past 5 years, we have provided a focal point for this effort, and today we are seeing the results of the hard work of the many individuals and groups working collaboratively to make medical device interoperability a reality. Ultimately, the national health IT agenda led by the White House and the ONC needs to make medical devices an explicit focus of the interoperability mantra. That would likely provide the tipping point for achieving success. **IPSQH**

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Go to <http://www.mdpnp.org>

Susan Whitehead is the program manager of the Medical Device Plug-and-Play (MD PnP) Interoperability program at CIMIT (Center for Integration of Medicine and Innovative Technology), a consortium based at Partners HealthCare in Boston. She coordinates collaborations, communications, and projects for the interdisciplinary, multi-institutional MD PnP program, which includes a growing network of more than 700 individuals and 90 institutions. Whitehead may be contacted at swhitehead@partners.org.

Julian Goldman is the medical director of Partners HealthCare Biomedical Engineering, director of the program on interoperability at CIMIT (Center for Integration of Medicine and Innovative Technology), and a practicing anesthesiologist in the Massachusetts General Hospital (MGH) "OR of the Future." He is the director of the Medical Device Plug-and-Play (MD PnP) Interoperability Program, which he founded in 2004 to lead the adoption of open standards and technology for networking medical devices to support high-acuity clinical solutions for improving patient safety and healthcare efficiency. Goldman may be contacted at www.jgoldman.info.



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**WEDNESDAY
PLENARY**

Patient Safety and Systems Engineering: What's Missing?

In an illuminating speech on Wednesday morning, anesthesiologist Julian M. Goldman, MD, issued a call for the application of systems engineering in the biomedical field. Dr. Goldman is the medical director of biomedical engineering for the Partners Health-Care System, the founding director of the program on Medical Device “Plug-and-Play” Interoperability (MD PnP) at the Center for Integration of Medicine and Innovative Technology (CIMIT), and an attending anesthesiologist at the Massachusetts General Hospital. At the symposium he was awarded the INCOSE Pioneer Award for his contributions to the MD PnP program, which he described in his plenary speech. For those participants in the audience unacquainted with technology in the context of modern medicine,

the talk served as an exposé of a deeply serious—indeed, a life-or-death—problem, one which only systems engineering may be adequately equipped to solve.

The problem, as Dr. Goldman explained, is that today’s medical systems “cannot be fully integrated due to the lack of interoperability” of medical devices and health information-technology systems, especially in “high-acuity” medical situations, such as hospital emergency rooms, operating rooms, intensive care units, and patient transport. For this reason, the motto for Dr. Goldman’s Medical Device “Plug-and-Play” Interoperability program is “Getting connected for patient safety.” The ability to integrate the clinical environment is crucial to creating error-resistant systems and accurate electronic medical records—and this cannot be done without device interoperability. The urgent need, then, is to find innovative system solutions to improve patient safety and health-care efficiency.

These solutions would need to answer several questions. First, how does one acquire health-care data comprehensively? Second, how does one support health-care workers in managing high-acuity patients? Hospital nurses, for example, often find themselves “running up and down” a hospital ward, because they have no other way of monitoring the vital signs and other data about different patients simultaneously. Third, how does one add error-resistance to the health-care system as a whole?

Today’s health-care systems have all the complexity of an aerospace or defense system, and highly visible human consequences, with none of the comprehensive systems engineering. Independent companies, which do not communicate with each other and are in direct competition, have developed proprietary devices and often actually seek to prevent their devices from working with those from other companies. A typical operating room, as Dr. Goldman illustrated with several photographs (figure 1), is crammed chaotically with electronic devices and medical apparatus, all connected by a rat’s nest of cables on the floor. Many of these use basic USB connectors with nothing to prevent them from being pulled out by someone tripping over a cable, which means that a surgeon performing laparoscopic surgery may lose the image at a crucial

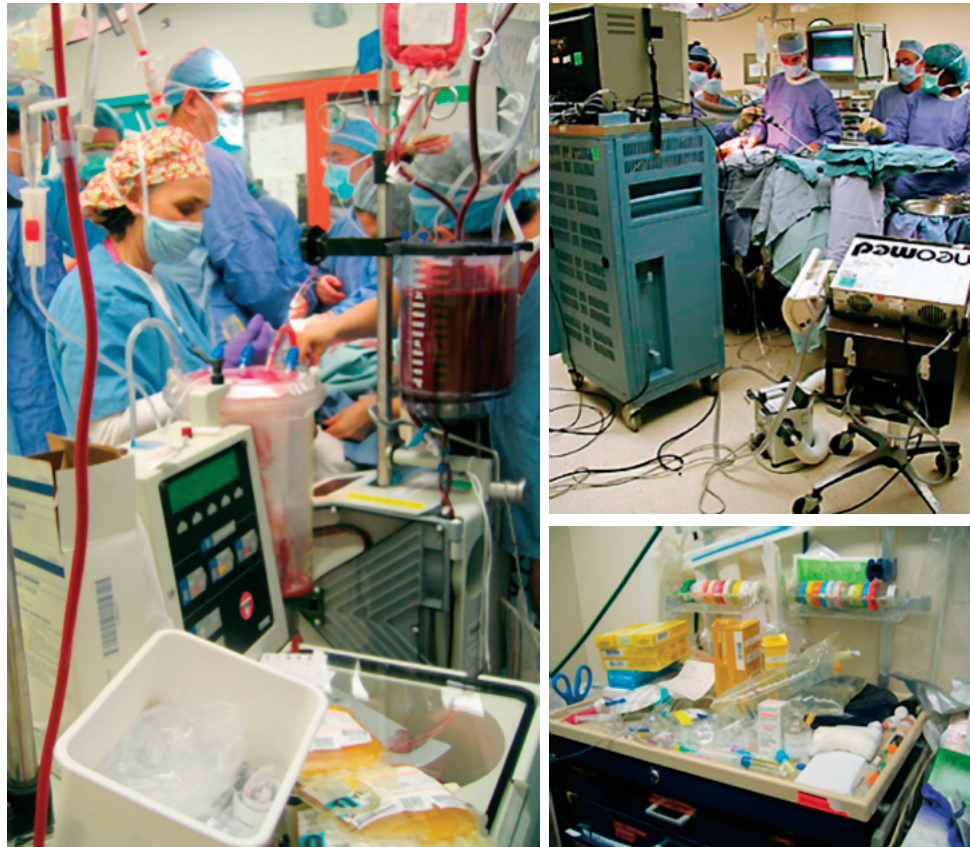


Figure 1. The technological complexity and disorder of a typical operating room (All photographs in this article by Julian Goldman)

moment in the operation—something that happens much more frequently than is recorded. The intensity of the operating room, especially in emergency situations, far outpaces the recording capabilities of any current system. It is currently impossible in practice for an anesthesiologist to check automatically to see if a patient has drug allergies before administering medications, and it is very difficult for anyone to record in real time all the drugs being administered during resuscitation.

Modern medical care is heavily dependent on complex technologies, but there is no way at present to integrate all the machines and devices necessary for a single patient's care, and as a result it becomes very difficult to identify and solve problems that may arise. This is critical, Dr. Goldman said, in military situations. For patients on board the US military's critical-care air transports (figure 2), there is no way to monitor all the systems (ventilators, IVs, etc.) connected to the patients—no single “dashboard” that could notify the physician when, say, one of the devices comes disconnected in the high-vibration environment of the plane.



Figure 2. US military critical-care air transport

There is no way at present to reliably and comprehensively track the movement of patients within an institution (from intake to intensive care to MRI testing to hospital room, for example). There is also no way to get an overall picture of an entire hospital's status (e.g., how many patients are on ventilators, the amount of their supply of a medication, the number of a particular device, or even simply how many suitable rooms are available). In the case of a large-scale emergency such as a hurricane, there is no way to know which hospital is able to receive patients that need to be evacuated.

The absence of integration produces waste and error on an appalling scale. One common problem is that devices produce false alarms, which become a nuisance to patients and medical workers rather than a help. Dr. Goldman said that during his own stay in the hospital for a cardiac arrhythmia, a device designed to monitor sepsis infection sounded its alarm continually, day and night. The device was built with an innovative algorithm to detect sepsis, but the machine was not connected to a source of data for several indicators (temperature, white-blood-cell count, glucose levels) that it needed to perform its calculations. As a result, the alarm continued to sound, and the medical staff's response was simply to keep turning the alarm off—once every hour.

Electronic medical-record systems now have a problem of incomplete data sets

and erroneous data. Incorrect clinical data may be entered automatically into the patient's permanent electronic record, producing compounding chains of confusion for those looking at the records afterward. Electronic record-keeping promises to be an improvement over previous methods (eliminating problems such as illegible handwriting and records written after the fact with imprecise data), but only when the data entering the system is accurate. In one case, two different devices were both recording a patient's pulse rate, using different algorithms to calculate it. When one device began to read over one hundred beats per minute faster than the other due to a faulty analysis of wave-form data, both pulse rates were entered into the permanent record, creating the appearance of a drastically fluctuating pulse. Since the original wave-form data cannot presently be stored in an electronic medical record, those viewing the record have no way to know that the pulse reading was an error, and no way to check the calculations against the original input (figure 3).

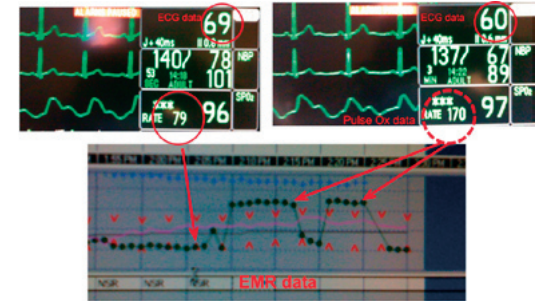


Figure 3. This medical device has misread its sensors and inserted false data into patient's permanent medical record.

Another problem occurs when multiple medical devices are not synchronized to the same clock time, resulting in untrustworthy time stamps in the permanent record, which could make it impossible to determine the actual effect of drug administration or other procedures. Dr. Goldman also described his experience attempting to use data from a new, high-tech peripheral nerve stimulator, only to find out that the data output had been encrypted and no one had access to the key.

The goal of integrating medical systems, Dr. Goldman argued, should be to resolve the kind of unmet needs described above: first, to provide complete data sets and documentation, both in real time for point-of-care support and for other, less urgent but equally important, activities such as metrics and management. Second, integration should make it possible to maintain comprehensive and current inventories of medical devices and their status, as well as real-time records of hospital occupancy and patient status. For example, he asked, is the United States able to monitor the condition of the equipment in its national stockpile of medical devices to ensure that they are ready to use? With current levels of technology integration (or dis-integration), it is hard to imagine that this would be possible.

Dr. Goldman offered some more examples of integration problems that increase the cognitive load of medical staff without providing much benefit. One company has recently designed a device that presents medical staff with a checklist from the World Health Organization for steps that must be performed before surgery;

the checklist is on a touchscreen right above the patient on the operating table so the staff have easy access to it. One of the items on the checklist is to verify that the pulse oximeter is on and functioning. The device also provides a readout of the patient's vital signs that includes the output of the pulse oximeter. So why can't the device read its own data and determine for itself whether the oximeter is functioning? Why, Dr. Goldman asked, do medical staff have to physically check a box that the system could check automatically? The reason is that the device is not interoperable with the pulse oximeter, so that it cannot actually read the oximeter output; instead, it just reproduces the visual output of the oximeter without being able to parse the data behind it. Instead of simplifying the process of preparing for surgery, the device ends up just adding one more step for personnel to follow.

Another device, designed to monitor heart rate and blood pressure, rang an alarm for asystole (no heart beat) because of a transient noise in the EKG signal, even while the same device displayed normal blood pressure and oxygen saturation waveforms (figure 4). It is because of false alarms and nuisance alarms like this that 70 percent of anesthesiologists turn off the alarms on their machines in the operating room. (One also cannot help but wonder why asystole—the most serious medical alarm there could be—should receive equal space on the display with the No Paper alarm.) The constant false alarms often create “alarm fatigue” among hospital staff, and in one recent case at Dr. Goldman's own hospital, Massachusetts General, a patient died because a heart alarm had been turned off. The ECRI Institute, the equivalent of *Consumer Reports* for medical devices, listed alarms on patient-monitoring devices as the second highest health-technology hazard in 2009.

Alarms on medical devices should be a good thing, Dr. Goldman said, much the way an alarm keeps an airline pilot from landing without first lowering the landing gear. But the alarms need to have “contextual awareness” that connects them to the data from multiple devices and keeps them from turning on erroneously. Integration of the whole medical system would close the workflow loop and identify missing steps and incomplete data; it would allow for safety interlocks that prevent tragic errors. Integrating medical systems—in particular their alarm

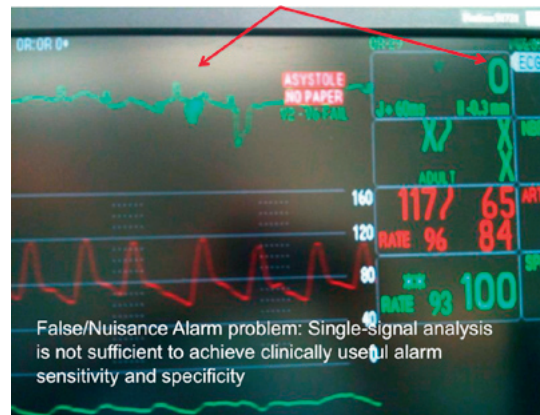


Figure 4. This device is displaying an alarm indicating that the patient has no heartbeat, but the same screen shows normal blood-pressure and oxygen-saturation waveforms produced by the normal heartbeat. Perhaps the No Paper alarm is more reliable.

systems—need not limit the freedom of the human operators by making everything automatic. While it is true that airplanes are required to sound an alarm if they sense that they are landing without having the landing gear down, there is also what Dr. Goldman called “the Hudson River override” so that the pilot can make a water landing without the distraction of the alarm if necessary. Medical devices should have warning systems that are as reliable as those of an aircraft, he said, but that also allow the same kind of freedom to the user.

Dr. Goldman then identified some specific problems that could be solved with better systems integration. In the common procedure of a cardiopulmonary (heart-lung) bypass, an anesthesiologist must first put the patient on a ventilator, then turn off the ventilator and turn on the bypass machine, and then finally turn off the bypass machine and turn the ventilator back on. According to Dr. Goldman, almost every anesthesiologist has on occasion forgotten (at least briefly) to turn the ventilator back on in the end, and in at least one documented case, the patient died. The simple way to prevent this error would be to have an alarm that would notify the anesthesiologist when both machines are turned off—but this is not now possible without greater integration.

In a similar situation, anesthesiologists often must briefly stop a ventilator so that a doctor can take an X-ray without the distorting motion of the lungs; in at least one published case, the anesthesiologist became distracted by another problem in the operating room and forgot to turn the ventilator back on, and the patient later died. According to Dr. Goldman, the ventilator and the X-ray ought to be connected in such a way that the ventilator automatically restarts when the X-ray is complete. Such a solution is not commercially available today, even though a prototype was demonstrated eleven years ago.

Doctors and health-care workers, Dr. Goldman stressed, do not have the time or leisure “to step back and look at the system issues: other people have to help them do it.” Dr. Goldman and his colleagues are providing that help through his Medical Device “Plug-and-Play” Interoperability Lab in Cambridge, Massachusetts (US). The lab was founded by Massachusetts General Hospital and CIMIT, with support from the US Army's Telemedicine and Advanced Technology Research Center and from Partners HealthCare Information Systems. By providing a neutral environment to bring together researchers from various institutions and industrial firms, the lab aims “to lead the adoption of open standards and technology for medical device interoperability to improve patient safety.” Already, researchers at the lab have produced a demonstration that shows how interoperability could solve the X-ray/ventilator problem.

The goals of the “Plug-and-Play” program are ambitious:

1. Lead the adoption of open standards and related technology to support medical-device interoperability and system solutions.

2. Define a regulatory pathway in partnership with the US Food and Drug Administration.
3. Elicit clinical requirements for the proposed interoperable solutions.
4. Use the vendor-neutral laboratory to
 - (a) evaluate interoperability standards and solutions, and
 - (b) serve as a community resource.
5. Investigate the safety of proposed engineering solutions.

In collaboration with Johns Hopkins University, Kaiser Permanente, and Partners HealthCare, the program has produced a document called MD FIRE, *Medical Device Free Interoperability Requirements for the Enterprise*. The document conveys the needs of health care to industry so that the producers of medical devices can understand what their customers are seeking. The document is specific about its goals: “We believe that changing the way in which we procure medical devices to integrate requirements for interoperability will provide a way for us to ensure


patient safety, improve healthcare quality, reduce healthcare costs, and provide for more comprehensive and secure management of health information.” The document can be downloaded at the program’s website, <http://www.mdnp.org>.

Dr. Goldman’s program has also worked with industry and others to develop a new standard, the Integrated Clinical Environment (ICE) standard ASTM F2761 (2009). The full title is *Essential Safety Requirements for Equipment Comprising the Patient-centric Integrated Clinical Environment (ICE): Part 1, General Requirements and Conceptual Model*. It is also available for download from the project’s website. To mediate between the patient and clinician, ICE inserts an ICE supervisor, network controller, and interfaces (figure 5). The ICE system also includes a data logger to record all data going through the network. This is necessary to provide forensic data for legal liabilities that could arise and jeopardize the whole project if something were to go wrong with a patient being treated under this system. An external interface connects the ICE system to the hospital’s own data system. The document includes six clinical-context scenarios, including the X-ray/ventilator synchronization problem discussed above.

In addition to the technological problems already mentioned, several other obstacles currently threaten the MD PnP program’s goals. First, those developing interoperable medical systems need to follow a defined regulatory pathway. CIMIT/MD PnP, the Continua Health Alliance, and the US Food and Drug Administration recently held a workshop to examine issues related to the regulatory pathway for interoperable device systems. As follow-up, workshop participants decided to develop a prototype regulatory submission of interoperable equipment using a specific clinical-use case, which will hopefully serve as a paradigm for further development.

Second, those working toward interoperability will have to win the support and cooperation of the medical-device industry. As long as companies put proprietary concerns before patient safety, the problem of “siloes” design and poor interoperability will continue to prevail.

Third, linking up the data from multiple medical devices into an integrated system has the potential to create privacy concerns that could easily derail the entire project. The ICE standard specifies a number of privacy requirements, but Dr. Goldman acknowledged that more thought still needs to be given to how to protect patients’ data in an interoperable environment.

Dr. Goldman welcomed INCOSE’s involvement in every aspect of his project. The task of improving patient safety and health-care efficiency, he said, is “a systems problem,” surely one of the most pressing challenges that systems engineering can address. INCOSE’s international scope can also help extend this project beyond just the United States to improve medical care around the world. 

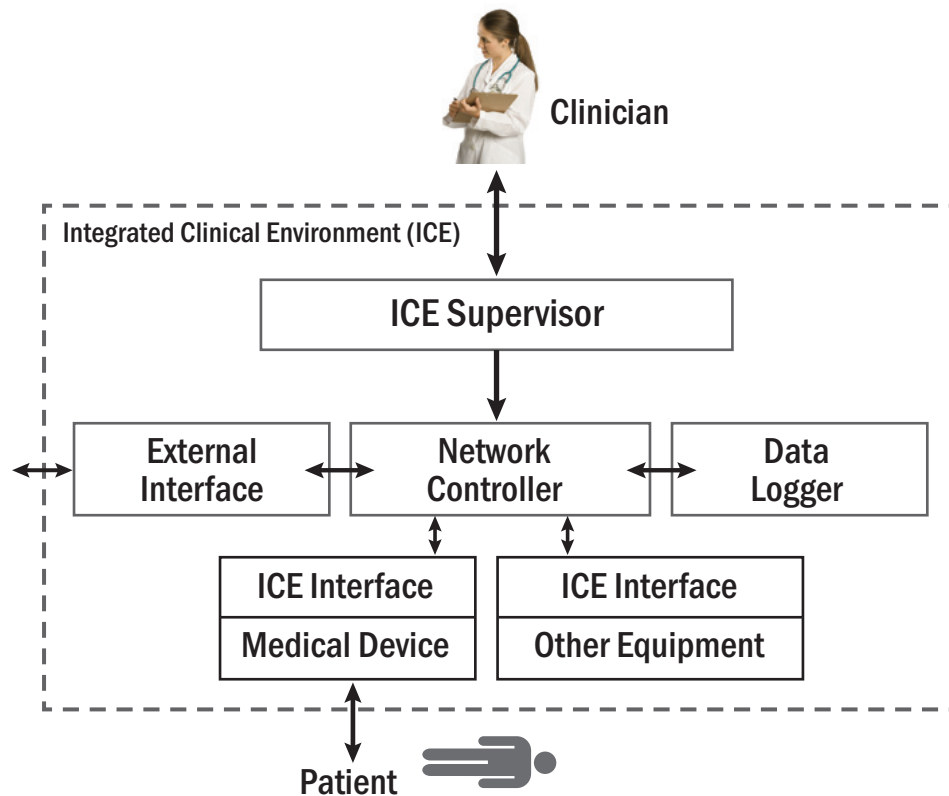


Figure 5. Functional elements of the integrated clinical environment

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The absence of open standards and related technologies for medical device integration is impeding national efforts to revolutionize the delivery of safe, efficient, high-acuity patient care. Many of the anticipated benefits that could be achieved through integrating devices and IT systems of different vendors remain theoretical: they cannot be deployed clinically because an infrastructure to create these integrated clinical systems does not exist, nor is there a framework or methodology to assess the safety and suitability of innovative solutions that would benefit from the healthcare intranet infrastructure. Just as the Internet enabled the development of the World Wide Web and revolutionized communication, collaboration, and commerce, a healthcare intranet is needed to provide a platform to develop broad innovations in the safety and efficiency of healthcare delivery. Creation of an open, standards based healthcare intranet is the equivalent of a "medical moonshot" that, as with Web 2.0, will empower the global healthcare community to build smart "integrated" clinical environments by contributing innovative interoperable technologies and clinical knowledge to improve healthcare.

This project will develop a prototype healthcare intranet by providing the necessary software and clinical expertise. Building on existing interdisciplinary collaborations, a multi-institutional team will develop a plug-and-play open platform for medical device connectivity, as well as software tools to ensure the safe and effective connectivity of medical equipment and decision support engines to support clinical care. A vendor-neutral laboratory will be developed to integrate the building blocks provided by collaborators and to implement a set of clinical use cases to assess the intranet capabilities. Our approach includes (1) select and analyze clinical scenarios, (2) assess existing network technologies that can be adapted, (3) develop new software for the proposed healthcare intranet, incorporating best practices from successful interoperability efforts in other environments, (4) implement these systems in the MD PnP Interoperability Lab, and (5) perform workflow evaluations and formal validation with use cases in a pre-clinical (lab) setting. The lab will serve long-term as a national resource for medical device interoperability R&D, testing and validation.